DEXAMETHASONE SOLUTION - dexamethasone solution

MWI/VetOne

CAUTION

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION

Dexamethasone Solution is a synthetic analogue of prednisolone, having similar but more potent anti-inflammatory therapuetic action and diversified hormonal and metabolic effects. Modification of the basic corticoid structure as achieved in Dexamethasone offers enhanced anti-inflammatory effect compared to older corticosteroids. The dosage of Dexamethasone required is markedly lower than that of prednisone and prednisolone.

Dexamethasone is not species-specific; however, the veterinarian should read the sections on INDICATIONS, DOSAGE, SIDE EFFECTS, CONTRAINDICATIONS, PRECAUTIONS, and WARNINGS before this drug is used. Dexamethasone is intended for intravenous or intramuscular adiminstration.

Each mL contains 2 mg dexamethasone, 500 mg propylethylene glycol 400, 9 mg benzyl alcohol, 1.8 mg methylparaben and 0.2 mg propylparaben as preservatives, 4.75% alcohol, HCl to adjust pH to approximately 4.9, water for injection q.s.

EXPERIMENTAL STUDIES

Experimental animal studies on dexamethasone have revealed it possesses greater anti-inflammatory activity than many steroids. Veterinary clinical evidence indicates dexamethasone has approximately 20 times the anti-inflammatory activity as prednisolone and 70 to 80 times that of hydrocortisone. Thymus involution studies show dexamethasone possesses 25 times the activity of prednisolone. In reference to mineralcorticoid activity, dexamethasone does not cause significant sodium or water retention. Metabolic balance studies show that animals on controlled and limited protein intake will exhibit nitrogen losses on exceedingly high dosages.

INDICATIONS

Dexamethasone is indicated for the treatment of primary bovine ketosis and as an anti-inflammatory agent in the bovine and equine. As supportive therapy, Dexamethasone may be used in the management of various rheumatic, allergic, dermatologic, and other diseases known to be responsive to anti-inflammatory corticosteroids. Dexamethasone may be used intravenously as supportive therapy when an immediate hormonal response is required.

Bovine Ketosis

Dexamethasone is offered for the treatment of primary ketosis. The gluconeogenic effects of Dexamethasone, when administered intramuscularly, are generally noted within the first 6 to 12 hours. When Dexamethasone is used intravenously, the effects may be noted sooner. Blood sugar levels rise to normal levels within 12 to 24 hours. Acetone bodies are reduced to normal concentrations usually within 24 hours. The physical attitude of animals and appetite improves, usually within 12 hours. Milk production, which is suppressed as a compensatory reaction in this condition, begins to increase. In some instances, it may even surpass previous peaks. The recovery process usually takes from 3 to 7 days.

Supportive Therapy

Dexamethasone may be used a supportive therapy in mastitis, metritis, traumatic gastritis, and pyelonephritis, while appropriate primary therapy is administered. In these cases, the corticosteroid combats accompanying stress and enhances the feeling of general well-being.

Dexamethasone may also be used as supportive therapy in inflammatory conditions such as arthritic conditions, snake bite, acute mastitis, shipping fever, pneumonia, laminitis, and retained placenta.

Equine

Dexamethasone is indicated for the treatment of acute musculoskeletal inflammations, such as bursitis, carpitis, osselets, tendonitis, myositis, and sprains. If boney changes exist in any of these conditions, joints, or accessory structures, a response to Dexamethasone cannot be expected. In addition, Dexamethasone may be used as supportive therapy in fatigue, heat exhaustion, influenza, laminitis, and retained placenta provided that the primary cause is determined and corrected.

ADMINISTRATION AND DOSAGE

Therapy with Dexamethasone, as with any other potent corticosteroid, should be individualized accordingly to the severity of the condition being treated, anticipated duration of steroid therapy, and animal's threshold or tolerance for steroid excess. Treatment may be changed over to Dexamethasone from any other glucocorticoid with proper reduction or adjustment of dosage.

Bovine: Dexamethasone: 5-20mg intravenously or intramuscularly. Equine: Dexamethasone: 2.5-5mg intravenously or intramuscularly.

CONTRAINDICATIONS

Except for emergency therapy, do not use in animals with chronic nephritis and hyper-corticalism (Cushing's Syndrome). Existence of congestive heart failure, diabetes, and osteoporosis are relative contraindications. Do not use in viral infections during the viremic stage.

PRECAUTIONS

Animals receiving Dexamethasone should be under close observation. Because of the anti-inflammatory action of corticosteroids, sign of infection may be masked and it may be necessary to stop treatment until a further diagnosis is made. Overdosage of some glucocorticoids may result in sodium retention, fluid retention, potassium loss, and weight gain.

Dexamethasone may be administered to animals with acute or chronic bacterial infections providing the infections are controlled with appropriate antibiotic or chemotherapeutic agents.

Doses greater than those recommended in horses may produce transient drowsiness or lethargy in some horses. The lethargy usually abates in 24 hours.

use of corticosteroids, depending on the dose, duration, and specified steroid, may result in inhibition of endogenous steroid production following drug withdrawal. In patients presently receiving or recently withdrawn from systemic corticosteroid treatments, therapy with a rapidly acting corticosteroid should be considered in unusually stressful situations.

WARNINGS

Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

Additionally, corticosteroids administered to dogs, rabbits, and rodents during pregnancy have produced cleft palate. Other congenital anomalies including deformed forelegs, phocomelia, and anasarca have been reported in offspring of dogs which received corticosteroids during pregnancy.

A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for yeal.

SIDE EFFECTS

Side effects, such as SAP and SGPT enzyme elevations, wieght loss, anorexia, polydipsia, and polyuria, have occurred following the use of synthetic corticosteroids in dogs. Vomiting and diarrhea (occasionally bloody) have been observed in cats and dogs. Cushing's Syndrome in dogs has been reported in association with prolonged or repeated steroid therapy. Corticosteroids reportedly cause laminitis in horses.

HOW SUPPLIED

Dexamethasone, 2mg per mL, 100mL multiple dose vial.

STORAGE

Store between 2degree C and 30degree C (36degree F and 86degree F).

PACKAGE LABEL PRICIPLE DISPLAY PANEL

NDC 13985-037-02

100 mL

VetOne

Dexamethasone Solution

Sterile Vial (2mg/mL)

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FOR ANIMAL USE ONLY

KEEP OUT OF REACH OF CHILDREN ANADA # 200-312, Approved by FDA

Net Contents: 100mL

EACH ML CONTAINS: 2 mg dexamethasone, 500 mg polyethylene glycol 400, 9 mg

VET ONE

100 mL

Dexamethasone

benzyl alcohol, 1.8 mg mettylparaben and 0.2 mg propylparaben as preservatives, 4.75% alcohol, HCI to adjust pH to approximately 4.9, water for injection q.s.

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idian, ID 83680 Distributed by:

ANADA# 200-312, Approved by FDA M 501012

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USUAL DOSE: Bovine - 5 to 20 mg Equine - 2.5 to 5 mg

For intravenous or intramuscular injection

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